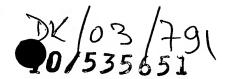
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Applicant:

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Denmark

Title: Device for measuring opening pressure for restrictions in bodily cavities.

(Indretning til måling i kropskaviteter)

IPC: A 61 B 5/107; A 61 B 8/12

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.



Patent- og Varemærkestyrelsen Økonomi- og Erhvervsministeriet

04 December 2003

Henrik Grye Skou

PATENT- G VAREMÆRKESTYRELSEN

## Patentansøgning

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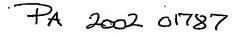
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4. Ansøger (fulde navn, adresse og evt. CVR-nr.): Rhinometrics A/S Industrivej 9 3550 Lynge	An 3379	☐ Flere ansøgere på bagsiden	www.dkpto.dk
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5. Fuldmægtig (navn og adresse): Mikael T. Christensen c/o Otlcon A/S Strandvejen 58 2900 Hellerup Telefon:39177100	Telefax:	39277900	<ol> <li>Gebyrer:</li> <li>Ansøgningsgebyr</li> <li>Kravgebyr</li> <li>ITS-nyhedsundersøgelsesgeby</li> </ol>
6. Opfinder (fornavn, efternavn, adresse): Steen B. Rasmussen Rhinometrics A/S Industrivej 9 3550 Lynge		,	•
6a. Opfinder (fornavn, efternavn, adresse): Peter Foged Christensen Rhinometrics A/S Industrivej 9 3550 Lynge	□ Flere o	opfindere på bagsiden	i .
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#### TITLE

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Device for measuring opening pressure for restrictions in bodily cavities

#### **BACKGROUND OF THE INVENTION**

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The present invention relates to the examination and measurement of constrictions or passages in cavities.

- For examination and measurement of blockings, deformations, movements etc. in various human and animal cavities, e.g. pharynx, larynx and other air and alimentary passages, urinary passages, arteries etc. various methods are known.
- From US 5823965 a device and a method are known, which comprise a catheter with a

  flexible measuring zone. The device may comprise means for establishing a positive
  pressure with the purpose of dilating the flexible measuring zone.

#### SUMMARY OF THE INVENTION

- The invention aims towards providing improvement in determining the opening pressure necessary for the opening of the restrictions for establishing a passage pass the restriction.
- According to the invention this is achieved by means of the device as defined in claim 1.

  By means of this device it is possible to obtain relatively detailed information of the opening pressure necessary.
  - A pressure transducer may be provided for obtaining values of the pressure condition in the catheter. Alternatively the pressure could be monitored using a pressure manometer.
  - The invention further relates to a method for determining the opening pressure of a restriction in a bodily cavity, the method comprising insertion of a catheter into the

cavity beyond the restriction, providing a positive pressure in the catheter by increasing the pressure by an increment and monitoring the pressure in the catheter.

The opening pressure is preferably determined from a sudden pressure drop occurring in the catheter due to an increase of the pressure increase provided by the pump. The pressure values may for this purpose be transmitted to a signal processing device sampling the pressure values and determining a sudden pressure drop.

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In preferred embodiments of the method, the cavity is an organic cavity, e.g. the respiratory passages, the blood or lymph tracts, the alimentary canal, or the urinary system or sections thereof of an animal or a human body.

Other features and advantages of the present invention will become apparent from the following description of embodiments of the invention, which refers to the accompanying drawings.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a block diagram of the basic lay-out of the device according to the an embodiment of invention;

FIG. 2 is a perspective drawing of part of the catheter, at the spot where the measurement is made;

25 FIG. 3 is a schematic drawing of a catheter in a cavity in different states of inflation;

## DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

FIG. I shows the basic lay-out of the device according to the invention.

As seen in FIG. 1, there is shown a catheter 1, the design of which will be explained below. At its proximal end A, the catheter 1 of a manner known per se, not illustrated, is connected to auxiliary equipment used for inserting the catheter in, e.g., the air passages

of a patient, through the mouth or the nostrils, or in the urinary system or an artery. The distal end of the catheter B, which after insertion, will be present in the cavity of the patient who undergoes an examination.

An electronic signal generator 2 is adapted to give an activation signal to a transducer 3 5 connected to the catheter 1. The signal generator 2 delivers the same signal to a signal analysis processor 4. A transducer 5 is connected to the catheter 1. When an excitation signal is transferred from the signal generator 2, via the transducer 3, to the interior of the catheter 1, this signal will propagate in the catheter, on to the distal end of the catheter, from where a response signal is sent back and received by the transducer 5 and 10 from there led to the signal analysis processor 4. The system comprises a pump 40 capable of increasing the pressure in the catheter either continuously or by small increments through a tube 41. A valve for pressure release may be provided. Further a pressure transducer capable of measuring the pressure present in the catheter is provided. The data are preferably transmitted to a data collecting and processing device for further 15 processing and/or for display. The opening pressure analysis may be performed by a device as described above which is intended for reflectometry measurements or may be performed alone in a device without the elements intended for the reflectometry measurement.

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The signal analysis processor 4 is connected to a computer 6 by means of which it is possible on a screen 7 to present an image, which illustrates the results of the examination and measurements made.

- The transducer 3 can be an arbitrary type known per se, e.g. an electromagnetic transducer, an electrostatic transducer, a piezo-electric transducer, etc. Its task is to transform the electronic signal from the signal generator 2 into an excitation signal in the interior of the catheter 1.
- The transducer 5 can also be of the above mentioned arbitrary type, e.g. a microphone, the purpose of which is to receive an acoustic response signal from the distal end of the catheter and to transform this response signal into an electric signal which is led to the signal analysis processor 4.

The analysis itself of the response signal in relation to the excitation signal belongs to a technique known per se.

A transducer 20 has been introduced from the outside through the outer chamber 12 and through the wall 15 so that the response signal receiving end 21 of the transducer 20 is located in the lumen 11.

Obviously medical or surgical considerations decide the choice of the inner and outer dimensions of the catheter which is the reason why the catheter is manufactured in different sizes as well as and lengths.

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From FIG. 3 three different states of inflation of the catheter is depicted. In the first state (A) the catheter is inserted to a position beyond the restriction. The catheter has not been been subjected to inflation. In state B the catheter has been inflated to a condition where the catheter on the outer side of the restriction has been inflated. The restriction prevents the pressure to propagate beyond the restriction. At a certain pressure the restriction cannot resist the pressure and an opening of the restriction will take place as indicated in state C in FIG. 3. The pressure medium will fill the entire volume of the catheter and hence give rise to a pressure drop in the catheter.

Considering that these kinds of transducers, e.g. a piezoelectric transducer function in both directions, e.g. being applied an electric voltage in order to give a pressure signal, or receiving a pressure signal and give an electric signal, it is obvious that instead of two transducers 3 and 5 in FIG. 1 it is in principle possible to use one single transducer, in which case the signal generator 2 should be electronically designed in such a way that, when operated from the analysis unit 4 and the computer 6, it firstly gives a transient signal and then transfers the response signal to the analysis unit. If a random or a pseudorandom signal is used as excitation signal, emitted continuously in the measurement period, two separate transducers will be used, as shown in FIG. 1.

It should also be added that the invention also offers the possibility of making prostate or

uterus examinations and similar examinations in bodily cavities like the urinary passage etc.

#### **CLAIMS**

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- 1. A device for measuring in bodily cavities, the device comprising a flexible catheter, a pump in connection with the catheter and adapted to provide a positive pressure to the catheter to inflate the catheter, where the pump is controllable to increase the pressure to the catheter.
- 2. A device according to claim 1, where the pump is controllable to increase the pressure in continuous manner.
- 3. A device according to claim 1, where the pump is controllable to increase the pressure in stepwise manner.
- 4. A device according to claim 1, where a pressure transducer is provided for obtaining values of the pressure condition in the catheter.
  - 5. A device according to claim 1, where the catheter at least in a measuring area comprises a flexible and essentially non-stretchable material capable of being introduced in the cavity beyond the restriction essentially without affecting the restriction.
  - 6. A device according to claim 5, where the catheter at least in a measuring area comprises a flexible and essentially non-stretchable material with a thickness of between 10 and 100 μm, preferably between 10 and 50 μm.

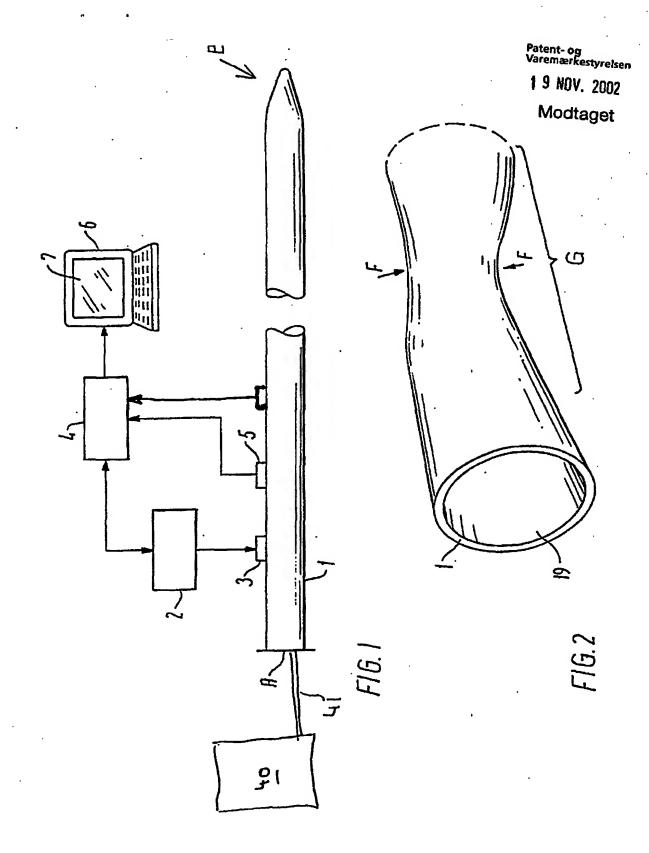
7. A method for determining the opening pressure of a restriction in a bodily cavity, the method comprising insertion of a catheter into the cavity beyond the restriction, providing a positive pressure in the catheter by increasing the pressure and monitoring the pressure in the catheter.

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- 8. A method according to claim 7, where the opening pressure is determined from a sudden pressure drop occurring in the catheter due to an increase of the pressure increase provided by the pump.
- 5 9. A method according to claim 7 or 8, where the pressure values are transmitted to a signal processing device sampling the pressure values and determining a sudden pressure drop.

#### **ABSTRACT**

The invention relates to a device for measuring in bodily cavities, the device comprising a flexible catheter, a pump in connection with the catheter and adapted to provide a positive pressure to the catheter to inflate the catheter, where the pump is controllable to increase the pressure to the catheter. The invention further relates to a method for determining the opening pressure of a restriction in a bodily cavity, the method comprising insertion of a catheter into the cavity beyond the restriction, providing a positive pressure in the catheter by increasing the pressure and monitoring the pressure in the catheter.

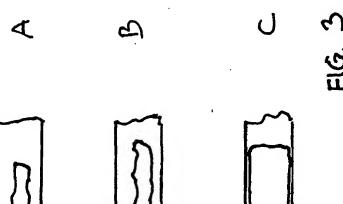


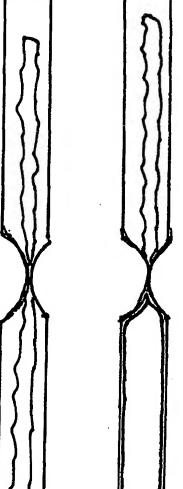
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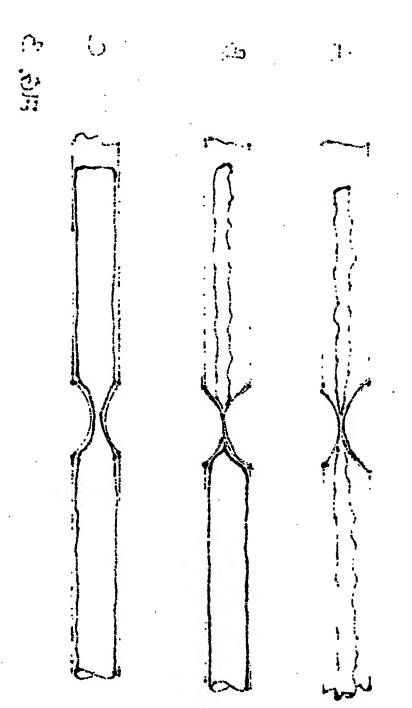
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